Updated Engagement Plan Template

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Introduction

PCORI requires meaningful engagement with stakeholder groups throughout the research process—from topic selection through design and conduct of research to dissemination of results. A well-thought-out engagement plan can facilitate the successful execution of an engaged research project. Recognizing that many aspects of a study's engagement plan may change or further develop between the submission of the research application and the start of a study, starting with Cycle 3 2016 awardees, PCORI requests that awardees update their engagement plan within the project's first six months.

The purpose of this template is to:

- Guide the study team in refining the original engagement plan that was submitted as part of the application. The study's updated engagement plan should serve as a useful resource that aids the team in fulfilling the objectives of a patient- and stakeholder-engaged clinical research project.
- Assist PCORI in documenting engagement activities at the project level in order to explore the influence and impact of engagement on study outcomes.

Instructions

This template is divided into sections that PCORI has found to be important components of stakeholder engagement in patient-centered outcomes research. All sections of this template should be completed to the best of your ability and to the extent they are applicable to the engagement plan for your project. PCORI does understand, however, that certain sections may not apply to your project design based on your study's unique needs, goals, and objectives. Please indicate "N/A" in sections that are not applicable.

Please fill out this template and submit it as an attachment to the "Submit Updated Engagement Plan in PCORI Online" milestone in PCORI Online. This should be done on or before the milestone due date. Note that PCORI began requiring this milestone with Cycle 3 2016 awardees. Please contact your program officer and/or engagement officer if you have any questions or need clarification.

1. Background Information

Principal Investigator: Click or tap here to enter text.

Project Title: Click or tap here to enter text.

Contract ID Number: Click or tap here to enter text.

Stakeholders Engaged (check all that apply):

☐ Patients/Consumers

☐ Family Caregivers

☐ Patient/Caregiver Advocacy Organizations

☐ Community-Based Organizations

☐ Clinicians

☐ Clinics/Hospitals/Health System Representatives

☐ Purchasers

☐ Payers

☐ Life Sciences Industries

☐ Policy Makers

☐ Training Institutions

☐ Subject Matter Experts

☐ Other, Please Specify: Click or tap here to enter text.

Please consider each engaged group within your project in your responses. Click here for additional information about how PCORI defines stakeholders.

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2. Goals

An approach for arriving at a shared vision for engagement is to work with your study team and stakeholder partners in drafting engagement-specific goals for your study. In the process, think about critical study activities that would benefit from engagement.

- What are your engagement goals and what are the key activities that align with those goals? In other words, what does your study team hope to accomplish through engagement and how (e.g., develop strong patient/community partnerships to support future research, enhance study recruitment and retention strategies, explore innovative approaches to conducting engaged research, etc.)? **Respond below.**

- What are your partners' goals? What do they hope to gain from participating? If you aren't sure, we recommend having a conversation with your partners about what is motivating their involvement and what are the benefits they hope to achieve. Please include partners' goals as a part of their bios in the next section.

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3. Partner Roster, Bios, and Roles

Provide a roster of members of the patient and stakeholder advisory bodies (e.g., patient advisory board, stakeholder advisory committee) **or individuals who are advising the study team.** Within the roster, include a short bio for each member that describes their background and relevant experience, organizational affiliation (if applicable), role on the project (including any work groups they may be serving on) motivation for participating and projected activities. If you wish to use the PCORI Peoples and Places Template, it can be found here, otherwise please include a 3-5 sentence summary for each partner.

Partners should be made aware that PCORI recognizes the contributions of stakeholder partners by posting the individual names of partners on the study's project page on the PCORI website. If, for privacy reasons, partners elect not to be listed publicly on our website, please indicate this on the roster. An example of a PCORI project page that lists patient and stakeholder partners can be viewed here.

Please include the roster and bios below or as an attachment.

4. Engagement Structure

In order for PCORI to understand how engagement is integrated into study governance, please provide a diagram depicting patient and stakeholder advisory bodies or individuals and their relationship to study leadership, other study governance committees, and key consultants. This should be a comprehensive visual representation of all the entities involved in your study and should include stakeholders' and investigators' lines of communication and information flows, and how patient and other stakeholder partner groups report feedback to decision-making authorities on the study. If applicable, include project staff designated to plan and oversee engagement activities and integrate the contributions and perspectives of partners into the management of the study**.** Please share any relevant experience the project staff have had with engaging with stakeholders in research or resources they plan to reference for guidance.

Please note: complex engagement structures do not necessarily result in better engagement. The purpose of the diagram is to document the different engagement models and strategies in PCORI's portfolio.

Please include a diagram below or as an attachment.

5. Proposed Meeting and Key Activity Timeline

By outlining your meeting and key activity schedule, you can help the research team plan and prioritize engagement activities. Note that the frequency and types of meetings may vary according to each study's design and needs. For example, some projects may choose to hold meetings more frequently in the early stages of the study and reduce the frequency when needs are less intense.

Please provide a table below that includes the following:

- Type of meeting or key activity (e.g., patient advisory board, focus group, etc.)
- Frequency (e.g., monthly, quarterly, as needed)
- Setting or method (e.g., community, academic, virtual, newsletter)
- A few sentences explaining the purpose and intent of the meeting

Here is a table with instructive examples. You may use this table, adapt it, or create your own to complete your meeting and key activity timeline. **Please include your timeline below.**

6. Partner Preparation

<u>Orientation</u>: Orientations for partners can be helpful to level-set expectations and begin team-building. The content of the orientation will vary depending on the partner's role and responsibilities and previous experience with research. **Please answer the following questions**.

- How will the research team ensure that partners clearly understand the expectations of serving on a PCORI-funded project? [Note: if using memoranda of understanding, committee charters or agreements, or job descriptions, please attach a version to the completed template]

- What guidance will be provided to partners on how to communicate their concerns with team members (e.g., disagreements with team members, dominant partner perspectives, fulfilling time commitments, etc.)

Preparation: Any training or education provided to patient and stakeholder partners should align with your study design and how partners will be involved in the project. **Please address the questions below**.

- What kind of training or education, if any, will be provided to prepare partners for participation in your study's research process?

- What are your research team members doing, if anything, to learn best practices for working with partners of diverse background and limited research knowledge?

7. Recruitment and Retention

Please describe how patient and stakeholder engagement will support recruitment and retention. Depending on the structure and needs of your study, examples of patient and stakeholder activities could include providing input on the design of study materials, participating in the content of recruitment videos, pilot-testing the recruitment script and process, selecting recruitment sites, or troubleshooting recruitment challenges. **Please respond below**.

8. Process and Outcomes Monitoring

Consider assessing the effect engagement is having on the project as related to your specific engagement goals (See Section 2), as well as what effect engagement is having on your study team and partners. For example, some projects conduct annual surveys or feedback sessions to learn about what is working and not working in terms of the effectiveness of their engagement practices. Some projects may be measuring the effect that engagement is having on the study planning, conduct and dissemination, beyond what PCORI asks in the Interim Progress Reports. **Using the space below, please let PCORI know if your research team plans to evaluate engagement outcomes or processes to make improvements and maximize contributions from partners, and if so, how**.

PCORI has found the toolkits and resources included in this Additional Engagement Planning Resources and Recommendations helpful to research teams. Please note: these resources are available through the public domain and/or the PCORI website.